

**MTN 043 - B-PROTECTED: Mother-Infant Pair Study of Dapivirine Ring and PrEP in Breastfeeding
Data as of December 5, 2022**

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers

	Malawi Blantyre	Zimbabwe Zengeza	Uganda Kampala	SA Johannesburg	All Sites
Participants Enrolled	39	67	55	36	197
1. Social Harms Assessment Required and Expected	224	397	321	202	1144
Completed	224 (100.0%)	396 (99.7%)	321 (100.0%)	202 (100.0%)	1143 (99.9%)
Not Completed	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
2. Baseline Behavioral Assessment Required and Expected	39	67	55	36	197
Completed	39 (100.0%)	67 (100.0%)	55 (100.0%)	36 (100.0%)	197 (100.0%)
3. Followup Behavioral Assessment Required and Expected	74	132	108	67	381
Completed	74 (100.0%)	132 (100.0%)	108 (100.0%)	67 (100.0%)	381 (100.0%)
4. 3 Month Behavioral Assessment Required and Expected	37	66	54	35	192
Completed	37 (100.0%)	65 (98.5%)	54 (100.0%)	35 (100.0%)	191 (99.5%)
Not Completed	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
5. IDI Required and Expected	5	9	13	8	35
Completed	3 (60.0%)	0 (0.0%)	12 (92.3%)	4 (50.0%)	19 (54.3%)
Not Completed	2 (40.0%)	9 (100.0%)	1 (7.7%)	4 (50.0%)	16 (45.7%)
6. Baseline Infant Feeding Assessment Required and Expected	78	134	110	72	394
Completed	78 (100.0%)	134 (100.0%)	110 (100.0%)	72 (100.0%)	394 (100.0%)
7. Followup Infant Feeding Assessment Required and Expected	187	331	269	167	954
Completed	187 (100.0%)	329 (99.4%)	269 (100.0%)	167 (100.0%)	952 (99.8%)
Not Completed	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
8. Use of Vaginal Products Required and Expected	39	71	56	38	204
Completed	39 (100.0%)	71 (100.0%)	56 (100.0%)	38 (100.0%)	204 (100.0%)
9. Physical Exam Required and Expected	115	201	164	109	589
Completed	115 (100.0%)	200 (99.5%)	164 (100.0%)	109 (100.0%)	588 (99.8%)
Not Completed	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	1 (0.2%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

**MTN 043 - B-PROTECTED: Mother-Infant Pair Study of Dapivirine Ring and PrEP in Breastfeeding
Data as of December 5, 2022**

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers

	Malawi Blantyre	Zimbabwe Zengeza	Uganda Kampala	SA Johannesburg	All Sites
10. Pelvic Exam Required and Expected	115	200	164	107	586
Completed	115 (100.0%)	199 (99.5%)	164 (100.0%)	106 (99.1%)	584 (99.7%)
Not Completed	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.9%)	2 (0.3%)
11. Pregnancy Test Required and Expected	37	66	53	35	191
Completed	34 (91.9%)	65 (98.5%)	53 (100.0%)	33 (94.3%)	185 (96.9%)
Not Completed	3 (8.1%)	1 (1.5%)	0 (0.0%)	2 (5.7%)	6 (3.1%)
12. HIV-1 Test Required and Expected	111	198	162	102	573
Completed	104 (93.7%)	196 (99.0%)	160 (98.8%)	98 (96.1%)	558 (97.4%)
Not Completed	7 (6.3%)	2 (1.0%)	2 (1.2%)	4 (3.9%)	15 (2.6%)
13. Hepatitis B Surface Antigen Test Required and Expected	39	67	55	36	197
Completed	39 (100.0%)	67 (100.0%)	55 (100.0%)	36 (100.0%)	197 (100.0%)
14. Blood Serum Chemistry Required and Expected	76	133	109	72	390
Completed	76 (100.0%)	132 (99.2%)	109 (100.0%)	71 (98.6%)	388 (99.5%)
Not Completed	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (1.4%)	2 (0.5%)
15. Hematology Required and Expected	76	133	109	71	389
Completed	76 (100.0%)	132 (99.2%)	109 (100.0%)	70 (98.6%)	387 (99.5%)
Not Completed	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (1.4%)	2 (0.5%)
16. Syphilis Serology Required and Expected	39	67	55	36	197
Completed	39 (100.0%)	67 (100.0%)	55 (100.0%)	36 (100.0%)	197 (100.0%)
17. NAAT (Pelvic) for GC/CT/Trich Required and Expected	39	67	55	36	197
Completed	39 (100.0%)	67 (100.0%)	55 (100.0%)	36 (100.0%)	197 (100.0%)
18. Plasma Archive Required and Expected	39	67	55	36	197
Completed	39 (100.0%)	67 (100.0%)	55 (100.0%)	36 (100.0%)	197 (100.0%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

**MTN 043 - B-PROTECTED: Mother-Infant Pair Study of Dapivirine Ring and PrEP in Breastfeeding
Data as of December 5, 2022**

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers

	Malawi Blantyre	Zimbabwe Zengeza	Uganda Kampala	SA Johannesburg	All Sites
19. Dried Blood Spot for TFV-DP and FTC-TP drug levels Required and Expected (after Visit 2 Truvada group only)	93	168	133	88	482
Completed	93 (100.0%)	167 (99.4%)	132 (99.2%)	83 (94.3%)	475 (98.5%)
Not Completed	0 (0.0%)	1 (0.6%)	1 (0.8%)	5 (5.7%)	7 (1.5%)
20. Plasma for DPV Drug Levels Required and Expected (DPV group only)	170	295	243	150	858
Completed	170 (100.0%)	293 (99.3%)	243 (100.0%)	150 (100.0%)	856 (99.8%)
Not Completed	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
21. Breast Milk for Drug Levels Required and Expected	224	396	321	202	1143
Completed	223 (99.6%)	394 (99.5%)	321 (100.0%)	188 (93.1%)	1126 (98.5%)
Not Completed	1 (0.4%)	2 (0.5%)	0 (0.0%)	14 (6.9%)	17 (1.5%)
22. Vaginal Swab(s) for Microbiota Required and Expected	77	134	109	75	395
Completed	76 (98.7%)	132 (98.5%)	108 (99.1%)	70 (93.3%)	386 (97.7%)
Not Completed	1 (1.3%)	2 (1.5%)	1 (0.9%)	5 (6.7%)	9 (2.3%)
23. Vaginal Gram Stain Required and Expected	77	134	109	75	395
Completed	76 (98.7%)	132 (98.5%)	108 (99.1%)	70 (93.3%)	386 (97.7%)
Not Completed	1 (1.3%)	2 (1.5%)	1 (0.9%)	5 (6.7%)	9 (2.3%)
24. Vaginal Swab(s) for Biomarkers Required and Expected	77	134	109	75	395
Completed	76 (98.7%)	132 (98.5%)	108 (99.1%)	70 (93.3%)	386 (97.7%)
Not Completed	1 (1.3%)	2 (1.5%)	1 (0.9%)	5 (6.7%)	9 (2.3%)
25. Used Vaginal Ring Required and Expected	85	148	123	78	434
Completed	83 (97.6%)	146 (98.6%)	123 (100.0%)	77 (98.7%)	429 (98.8%)
Not Completed	2 (2.4%)	2 (1.4%)	0 (0.0%)	1 (1.3%)	5 (1.2%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.